Senate

General Assembly

File No. 194

February Session, 2002

Substitute Senate Bill No. 504

Senate, March 27, 2002

The Committee on General Law reported through SEN. COLAPIETRO of the 31st Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE REPORTING OF PRESCRIPTION ERRORS AND REQUIRING CERTAIN CONTINUING EDUCATION FOR PHARMACISTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2002*) (a) As used in this section:

(1) "Dispensing" means those acts of processing a drug for delivery or for administration for a patient pursuant to a prescription consisting of: (A) Comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug; (D) the placing of the drug in the proper container; (E) the affixing of the label to the container; and (F) the addition to a written prescription of any required notations;

(2) "Drug" means (A) an article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the

United States or official National Formulary, or any supplement to any of them, (B) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) an article, other than food, intended to affect the structure or any function of the body of humans;

(3) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594 of the general statutes. For the purposes of this section, "pharmacy" shall include any areas of an institutional pharmacy where prescription drugs are dispensed to outpatients, employees and retirees.

(4) "Prescribing practitioner" means an individual licensed by the state of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual's practice;

(5) "Prescription" means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug for a specific patient; and

(6) "Prescription error" means an act or omission of clinical significance relating to the dispensing of a drug that results in or may reasonably be expected to result in injury to or death of a patient.

(b) Each pharmacy shall display a sign concerning the reporting of prescription errors in a conspicuous location visible to consumers of prescription drugs. The sign shall measure a minimum of eight inches in height and ten inches in length and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the pharmacy prescription department distribution counter. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer

Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)".

(c) Each pharmacy that dispenses a prescription to a consumer shall include the following printed statement on or in the bag or other similar packaging in which the prescription is contained: "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)". The statement shall be printed in a size and style that allows such statement to be read without difficulty by consumers.

(d) The Commissioner of Consumer Protection shall adopt regulations, with the advice and assistance of the Commission of Pharmacy, in accordance with chapter 54 of the general statutes, concerning the implementation of a quality assurance program designed to detect, identify and prevent prescription errors in pharmacies. Such regulations shall require that each pharmacy implement a quality assurance program that describes in writing policies and procedures to be maintained in such pharmacy. Such policies and procedures shall include directions for communicating the details of a prescription error to the prescribing practitioner and to the patient, the patient's caregiver or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the prescription error or reducing the negative impact of the error on the patient. Such regulations shall require that records of all reported prescription errors shall be maintained at the applicable pharmacy for a minimum period of three years and that such records shall be made available for inspection by the Commissioner of Consumer Protection in any case where the commissioner is investigating a report of a prescription error.

Sec. 2. Subsection (a) of section 20-600 of the general statutes is

repealed and the following is substituted in lieu thereof (*Effective October 1, 2002*):

(a) Except as provided in subsections (b), (c), (f) and (g) of this section, the commission shall not authorize the department to renew a license to practice pharmacy as a pharmacist unless the pharmacist applying for the renewal submits a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed not less than fifteen contact hours of accredited continuing professional education in the previous calendar year immediately preceding expiration of the license. Not less than five contact hours of the annual continuing education requirement shall be earned by attendance at a live presentation of an accredited continuing professional education program. At least one of the five contact hours earned by attendance at a live presentation shall be on the subject matter of pharmacy law or drug law.

This act shall take effect as follows:	
Section 1	*October 1, 2002*
Sec. 2	*October 1, 2002*

Statement of Legislative Commissioners:
In subdivision (1) of subsection (a), "or device" was deleted for consistency. In subdivision (3) of subsection (a), "and devices" was deleted for consistency. In subsection (a), reference to section 20-600 of the general statutes was deleted for accuracy. In subsection (b), "font size and style" was changed to "size and style" for clarity. In subsection (d), "each quality assurance program" was changed to "each pharmacy implement a quality assurance program" for clarity and consistency.

GL *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

This bill requires the Commissioner of Consumer Protection to adopt regulations, with the advice and assistance of the Pharmacy Commission, requiring pharmacies to establish quality assurance programs designed to detect, identify and prevent prescription errors.

The bill primarily affects pharmacies and pharmacists. As such it would minimally affect the Department of Consumer Protection (DCP). The department anticipates that its passage would result in increased telephone calls, but such workload increase, as well as the adoption of regulations, can be accommodated by staff within their normal duties and responsibilities without the need for additional resources.

OLR Bill Analysis
sSB 504

AN ACT CONCERNING THE REPORTING OF PRESCRIPTION ERRORS AND REQUIRING CERTAIN CONTINUING EDUCATION FOR PHARMACISTS

SUMMARY:
This bill requires the consumer protection commissioner to adopt regulations requiring pharmacies to establish quality assurance programs designed to detect and prevent prescription errors. The bill defines a "prescription error" as an act or omission of clinical significance relating to the dispensing of a drug that results in, or may reasonably be expected to result in, a patient's injury or death. In addition, the bill requires each pharmacy to post signs and include notices in prescription packaging informing consumers of a way to report prescription errors.

EFFECTIVE DATE: October 1, 2002

QUALITY ASSURANCE PROGRAMS

The bill requires the consumer protection commissioner to adopt regulations, with the advice and assistance of the Pharmacy Commission, to require:

1. each pharmacy to implement a quality assurance program designed to detect, identify, and prevent prescription errors;
2. each such program to have written policies and procedures;
3. the policies to require the pharmacy to report the errors to the prescribing practitioner, the patient, the patient's caregiver or appropriate family member if the patient is deceased or unable to comprehend;
4. the error report to include ways of correcting or mitigating the error; and
5. records to be kept in the pharmacy for at least three years and available to inspection by the consumer protection commissioner in cases in which the commissioner is investigating an error report.

REQUIRED SIGN AND NOTICE

The bill requires each pharmacy to post an 8-by 10-inch sign in a conspicuous location stating, "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling [DCP's toll-free number]." The sign must use lettering that is of a size and style that allows a consumer standing at the prescription counter to read it without difficulty.

The bill requires pharmacies to include in each bag or packaging a notice containing the information that must be on the sign.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 17 Nay 0